Approved for use through 3/31/2007 - OMB 6851-0021 Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER 06276/HG

U.S. APPLICATION NO. (If known, see 373CFR 1.5) n 1576406

INTERNATIONAL APPLICATION NO. PCT/JP2004/016460

PRIORITY DATE CLAIMED

INTERNATIONAL FILING DATE 29 OCTOBER 2004 29 OCTOBER 2003; 10 NOVEMBER 2003 TITLE OF INVENTION THERAPEUTIC AGENT FOR KERATOCONJUNCTIVAL DISORDER APPLICANT(S) FOR DO/EO/US Masatsugu NAKAMURA; and Shin-ichiro HIRAI Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. X This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). X A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). b. X has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. X An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. l Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 19. Express Mail Label No. EV 842 303 327 US

Copy of: (i) NOTIFICATION PCT/IB/304; (ii) SECOND AND SUPPLEMENTARY NOTICE PCT/IB/308; (iii) NOTIFICATION PCT/IB/301; (iv) NOTIFICATION PCT/IB/311; (v) WO 2005/039571 A1 (title page only), the publication of PCT/JP2004/016460; (vi) English language INT. SEARCH REPORT; and (vii) REQUEST FOR PUBLICATION OF ASSIGNMENT INFORMATION.

Other items or information:

20. X

Date of Deposit: April 20, 2006 I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above with sufficient postage, and is addressed to the Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450

> 02 Lori Valdes

U.S. APPLICAT	ION NO. (if knowr	ATTORNEY'S DOCKET NUMBER									
	10/50	64UC	PCT/JP200	4/016460	06276	S/HG					
	owing fees have b	CALCULATIONS PTO USE ONLY									
21. 🙀 Basi	ic national fee	\$300	\$ 300.00								
If International property of the PCT Article 33	nination fee reliminary examina 3(1)-(4)	\$ 200.00									
Search fee (37 C Internatio International Sea All other situation	rch fee FR 1.445(a)(2)) h rnal Searching Aut irch Report prepar is	\$ 400.00 \$ <b>900.00</b>									
sequence lis	e for specification sting or computer										
The fee is \$2  Total Sheets	250 for each addit Extra Sheets	Number of eac	f paper or fraction thereof.  n additional 50 or fraction up to a whole number)	RATE							
17 - 100 =	0 /50 =		0	x \$250	\$ .00						
Surcharge of \$13	0.00 for furnishing ate (37 CFR 1.492	<del></del>	\$ .00								
CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$	<u> </u>					
Total claims	9	- 20 =	0	× \$50	\$ .00	1					
Independent clair	ns 3	-3=	0	x \$200	\$ .00	ĺ					
MULTIPLE DEPE	ENDENT CLAIM(S	(if applicable)		+ \$360	\$ .00						
			TOTAL OF ABOVE	CALCULATIONS =	\$ 900.00						
Applicant cla	ims small entity st	atus. See 37 CFF	R 1.27. Fees above are redu	ed by 1/2.							
		\$ 900.00									
	f §1 <b>30.00</b> for fumls ate (37 CFR 1.492	\$ .00									
		\$ 900.00									
	the enclosed assi cover sheet (37 (	\$ 40.00									
			TOTAL F	EES ENCLOSED =	\$ 940.00						
					Amount to be refunded:	\$ .00					
					Amount to be charged:	\$ .00					
a A check	k in the amount of	\$	to cover the abo	ve fees is enclosed							
a. A check in the amount of \$ to cover the above fees is enclosed.  b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.											
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1378. A duplicate copy of this sheat is enclosed.											
			ARNING: Information on this ard information and authorization		olic. Credit card Informat	ion should not					
NOTE: ₩here an and granted to n	appropriate timestore the interns	e limit under 37 atlonal Applicati	CFR 1.495 has not been me on to pending status.	t, a petition to revive	(37 CER 4.137(a) or (b))	must be filed					
SEND ALL CORF	RESPONDENCE	T////////	//h/								
CUSTOMER NO. 01933											
	ltz, Goodman	oodman									
	220 5TH AVE FL 16  NEW YORK NY 10001-7708  17,081  REGISTRATION NUMBER										
				NEGIO I RATII	OIT MOMBER						

# 10/5/6402

## JAP20 Reside Stiff 20 20 APR 2006

Express Mail Mailing Label

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(U.S. National Phase Appln. Appl. No.

based on PCT/JP2004/016460)

Masatsugu NAKAMURA et al Applicant

Filed Concomitantly herewith

THERAPEUTIC AGENT FOR For

KERATOCONJUNCTIVAL DISORDER

Docket No. 06276/HG

Customer No.: 01933

REQUEST FOR PUBLICATION OF ASSIGNMENT INFORMATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SIR:

No.: EV 842 303 327 US Date of Deposit: April 20, 2006 I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to

Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Lori Valdes

In the event that this Paper is late filed. and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by credit card payment, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

It is requested that the following assignment information be published as part of the 18-month publication of the present application:

> SANTEN PHARMACEUTICAL CO., LTD. 9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku Osaka-shi, Osaka 533-8651 Japan

Frishauf, Holtz, Goodman & Chick, P.C.

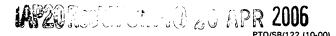
220 Fifth Ave., 16th floor New York, NY 10001-7708

Telephone: (212) 319-4900 Facsimile: (212) 319-5101

HG/lpv

Respectfully submitted,

GOODMAN Keg. No. 17,081



Please type a plus sign (+) inside this box  $\rightarrow$  [+]

Approved for use through 10/31/2002. OMB 0651-0035 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

#### 0/576402 **Application Number CHANGE OF CORRESPONDENCE ADDRESS** Filing Date Concomitantly herewith Application First Named Inventor M. NAKAMURA et al Address to: Group Art Unit **Commissioner for Patents** P.O. Box 1450 **Examiner Name** Alexandria, VA 22313-1450 Attorney Docket Number 06276/HG

Please change the Correspondence Address for the above-identified application to:											
[X] Customer Number [ 01933 ]											
OR											
[ ] Firm or Individual Name											
Address											
Address											
City		State			ZIP						
Country											
Telephone		Fa									
This form cannot be used to change the data associated with a Customer Number. To change the data associated with an existing Customer Number use "Request for Customer Number Data Change" (PTO/SB/124).											
I am the:											
[ ] Applicant/Inventor.											
[ ] Assignee of record of the entire interest. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).											
[X] Attorney or Agent of record.											
[ ] Registered practitioner named in the application transmittal letter in an application without an executed oath or declaration. See 37 CFR 1.33(a)(1). Registration Number											
Typed or Printed											
Name Herbert Goodman, Reg. No. 17,081											
Signature A A A A A A A A A A A A A A A A A A A											
Date April 20, 2006											
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required. See below.											